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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,685	04/22/2005	Einar Moen	Q-84077	4835

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EXAMINER	
SINGH, SATYENDRA K	
ART UNIT	**PAPER NUMBER**
1657	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,685	MOEN ET AL.	
	Examiner	Art Unit	
	Satyendra K. Singh	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-14 and 25-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-14 and 25-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 24th 2007 has been entered.

Claims 1-10 and 15-24 are cancelled by applicant's amendments to the claims.

Claims 11-14, 25-34 and newly added claim 35 (applicant's elected invention of group II) are being examined on their merits, herein.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28 and 29 (as currently presented) **are/remain** rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most connected, to make and/or use the invention.

The invention appears to employ novel biological material, bacterial strains (such as recited in instant claims 28 and 29). Since the biological materials (i.e. the claimed bacterial strains) are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological material is not so obtainable or available, the requirements of 35 U.S.C. §112 may be satisfied by a deposit of the biological material. The specification

does not disclose a repeatable process to obtain the biological material and it is not apparent if the biological material is readily available to the public.

It is noted that applicant has deposited the biological material (instant specification, page no. 3, second, full paragraph, in particular; and applicant's remarks filed on August 3rd 2006, page 6, last paragraph, in particular), but there is no indication in the specification as to **whether the deposit was made under Budapest treaty**. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological material (in the instant case, bacterial strains as recited in the instant claims 28 and 29) has been deposited under the Budapest Treaty and that the biological material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §1.801-1.809, applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the commissioner upon request;
(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. §1.807); and
(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. § 2400 in general, and specifically to § 2411.05, as well as to 37 C.F.R. §1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and **address of the depository**, and a description of the deposited material sufficient to specifically identify it and to permit examination". The specification should be amended to include this information, however, applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims11-14 and 25-35 (as currently amended) are rejected under 35 U.S.C. 103(a) as being unpatentable over Bothe et al (*Appl. Microbiol. Biotechnol.*, 2002; IDS) taken with Norferm, DA (Product brochure, 1998; IDS) and Larsen & Joergensen (*Appl. Microbiol. Biotechnol.*, 1996; IDS), and further in view of Atlas & Parks (Handbook of Microbiological Media, 1993 edition; [U]) and Patz et al (DD 290,917; IDS, an English translation was provided by the office in previous office action).

Claims are generally directed to a **microorganism growth substrate** (i.e. a composition or product) comprising a **sterilized nutrient composition** wherein said composition is **a biomass generated from** bacterial cells **comprising** at least one methanotrophic bacteria and at least one heterotrophic bacteria, and at least one **sterile nutrient**, which is a carbon source, added to the biomass, and **optionally** containing **a diluent** (see detailed recitation of instant claims 11-14 and 25-35).

> *"[E]ven though **product-by-process** claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).*

Bothe et al (IDS) disclose a composition (i.e. a bacterial biomass) comprising biomass generated from bacterial cells, wherein bacterial cells comprising at least one species of methanotrophic bacteria (such as *M. capsulatus* (Bath) NCIMB 11132) (see Bothe et al, abstract, page 34, materials & methods, in particular; and the disclosure of the protein-rich biomass obtained from said bacterium grown on methane as a carbon source, oxygen, ammonia, and minerals, and water in a reactor, and centrifuged, ultrafiltered, heat-inactivated, and finally spray-dried in the form of a free-flowing, granulated product that is suitable for various applications as a high protein and nutrient source; see Norferm, DA, product brochure, 1998) and at least one species of heterotrophic bacteria (such as *Ralstonia* sp., *Aneurinibacillus* sp., or *Brevibacillus* sp; see Bothe et al, abstract, pages 34, 35 and 38, in particular), at least one sterile nutrient (such as components of nitrate/mineral salts, NMS medium as described by Larsen & Joergensen; cited on page 138, left column, in particular).

However, a microorganism growth substrate comprising a sterilized nutrient, which is a carbon source, as specifically recited in claim 11, comprising at least one **sterile nutrient** added to the biomass, such as **glucose**, or a combination of nitrate and mineral salts that is present in a **weight ratio on a dry mass basis** (as specifically recited in instant claims), is not explicitly disclosed by the combined disclosures of Bothe et al (taken with Norferm, DA and Larsen & Joergensen).

Atlas & Parks [U] provides the detailed disclosure about various nutrient media compositions routinely used for the cultivation (on solid as well as liquid media) of methanotrophic and heterotrophic bacteria (see Atlas & parks, for various methanotrophic bacteria, pages 574-579; and for heterotrophs such as various lactic acid bacteria and *Lactobacillus* species, pages 483-488, in particular). Atlas & Parks teaches the use of **glucose as a sterile nutrient** for use in various media compositions

routinely used for cultivation of various microbial species (see Atlas & Parks, pages 576, 483-488, in particular), and also the use of **nitrate and mineral salts** (see Atlas & Parks, pages 574-575, in addition to the teachings from Larsen & Joergensen, page 138, left column, 1st paragraph, in particular) in the cultivation of microorganisms (being especially useful in the cultivation of methanotrophic bacteria).

Patz et al [U] teach a microorganism growth substrate comprising a sterile nutrient composition (**chemical thermal hydrolysate**; see Patz et al, page 3, substance of the invention, and page 5, first paragraph, and example 1, in particular) obtained from the biomass of a culture of bacteria including methanotrophic bacteria (a methylotrophic bacteria such as *Methylobacterium rhodesianum* IMET 11401; see Patz et al, page 1, claims and page 3, substance of the invention, in particular) further comprising at least one sterile nutrient (such as a carbon source, methanol; see Patz et al, , and optionally containing a diluent (such as water; see Patz et al, example 1 and 2, pages 6 and 7, in particular). Patz et al also teach sterile nutrient medium for fermentation of bacteria containing nitrate and mineral salts and combinations thereof (such as iron, copper, magnesium, manganese, zinc, nickel, boron, calcium, potassium, sodium, cobalt; see Patz et al, page 7, in particular).

Therefore, given the detailed disclosure for the components of the claimed composition in the cited prior art references, it would have been obvious to a person of ordinary skill in the art at the time this invention was made to modify the microorganism growth substrate composition of Bothe et al (taken with the disclosures of Norferm, DA and Larsen & Joergensen, as discussed above) such that the growth substrate

comprises a sterile nutrient as a carbon source, such as glucose, and further contains nitrate and mineral salts, and/or a combinations thereof, as explicitly suggested and disclosed by Atlas & parks [U].

The person of ordinary skill would be motivated to modify the growth substrate composition comprising the biomass generated from bacterial cultures (as taught by Bothe et al) because the sterile nutrient compositions containing glucose, nitrate and mineral salts have been routinely used in the cultivation of various microorganisms (methanotrophic as well as heterotrophic) as explicitly disclosed by Atlas & parks (see discussion, supra). Furthermore, given the disclosure of Patz et al for the use of a bacterial biomass (a methanotrophic **bacterial hydrolysate** used as a nutrient source; see disclosure above) for cultivation of bacteria, an artisan of ordinary skill in the fermentation art would be highly motivated to use this protein-rich biomass generated from methanotrophic bacteria, as a nutrient source when making a composition (or a culture medium) suitable for growth of microorganisms.

One of ordinary skill in the art would have had a reasonable expectation of success when modifying the composition according to the disclosures of Atlas & Parks and Patz et al, because the prior art references have explicitly disclosed the amounts, ratios and method of preparation of such growth media/substrate compositions that are useful in cultivation of various microorganisms.

Although, the cited prior art references do not explicitly teach a microorganism growth substrate composition wherein the sterile nutrient such as glucose, or a

combination of nitrate and mineral salts are present in specific **dry mass basis** (as recited in the instant claims) in relation to the biomass (obtained from the culture of methanotrophic and heterotrophic bacteria) used in the invention as claimed, such use of specific ratios of required nutrients (alone as well as in combinations thereof) in relation to the biomass used in the composition would have been a routine matter of optimization to a person of ordinary skill in the art (As evident by the fact that the optimum amounts of sterile nutrient such as glucose, and nitrate and mineral salts are explicitly disclosed by the referenced inventions of Larsen & Joergensen, Atlas & Parks and Patz et al; see discussions above). The selection of specific ratios to be used of the nutrient components (in relation to the biomass used) in the claimed growth substrate composition would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that it is a routine procedure to optimized the ratios of ingredients for the culture of any given individual microorganism (relative to other components or nutrients used in the composition) in order to obtain an optimum yield of specific cultured product or biomass. Furthermore, given the fact that sterile nutrients such as nitrate and mineral salts have been used by Bothe et al (in view of Larsen & Joergensen) in the cultivation of Methanotrophic bacteria (such as *Methylococcus capsulatus* (Bath) strain) using the composition as claimed, it would have been a matter of routine optimization of the medium composition as well as of specific ratios of the sterile nutrient in relation to the biomass used to arrive at an optimum growth substrate composition. Therefore, a holding of obviousness over the cited claims is required.

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time this invention was made.

As per MPEP 2144.05 [R3], II. OPTIMIZATION OF RANGES - A. Optimization Within Prior Art Conditions or Through Routine Experimentation: *Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).*

As per MPEP 2144.06, "*It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*

As per MPEP 2111.01, *during examination, the claims must be interpreted as broadly as their terms reasonably allow. In re American Academy of Science Tech Center, F.3d, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation.). This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

Obviousness-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 11-14 and 25-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 30 and 32-44 of

copending Application No. 10/504,464 (common inventors, same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because pending claims in said co-pending application are also directed to a product-by-process (i.e. a composition), which is derived from a biomass hydrolysate generated from the cultured biomass of a methanotrophic bacterium. Since, the two sets of pending claims are co-extensive in scope, an obviousness-type double patenting rejection is clearly required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 11-14 and 25-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8 and 13-27 of copending Application No. 10/504,463 (same inventive entity, same assignee). Although the conflicting claims are not identical, they are not patentably distinct from each other because pending claims in said co-pending application are also directed to a product-by-process (i.e. a composition), which is derived from a biomass autolysate generated from the cultured biomass of a methanotrophic bacterium. Since, the two sets of pending claims are co-extensive in scope, an obviousness-type double patenting rejection is clearly required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 11-14 and 25-35 (as they pertain to the prior art rejections of record) have been considered but are moot in view of the new ground(s) of rejections made in this office action.

Conclusion

NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyendra K. Singh whose telephone number is 571-272-8790. The examiner can normally be reached on 9-5MF (alternate Fridays OFF).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Satyendra K. Singh
Patent Examiner
Art Unit 1657

IRENE MARX
PRIMARY EXAMINER